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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,866	07/28/2003	Shukri F. Khuri	EMI-001CX	3828
207 7590 07/25/2008 WEINGARTEN, SCHÜRGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109				
EXAMINER NASSER, ROBERT L				
ART UNIT		PAPER NUMBER		
3735				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/628,866

Applicant(s)

KHURI ET AL.

Examiner

ROBERT L. NASSER

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-37 and 40-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-37 and 40-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 35-37, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by the Tantillo et al article entitled, "Myocardial tissue pH in the assessment of the extent of myocardial ischemia and the adequacy of myocardial protection. Tantillo discloses throughout a method including measuring the pH of the heart. Then on pages 344 and 345, 347-349, it teaches recognizing suboptimal pH levels of the heart, and delivering cold cardioplegia to one of a plurality of possible sites (i.e. aortic root of left main coronary artery) in response to low pH levels. Claim 35 is rejected in that if the delivery of cardioplegia is turned on and off, it is inherent that there is a valve. Claim 40 is rejected in that Tantillo tests the pH of myocardial tissue

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tantillo et al in view of Lee. Tantillo manually adjusts the delivery of the solution. Lee is selected from a myriad references that automates such a delivery, to remove human error. Hence, it would have been obvious to modify Tantillo to use a control, to increase the accuracy of the system. In addition, with respect to claim 36, it would have

been obvious to alert the physician by displaying to any changes occurring in such an automated procedure, to provide the physician with full knowledge of the status.

Claims 32 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tantillo. With respect to claim 32, the delivery of fluid goes from zero to a positive amount. Hence the flow rate is altered. It is the examiner's position that it would have been obvious to use a valve to perform the turning on and off of the flow. Claim 41 is rejected in that the examiner takes official notice that it is known to deliver electrodes to the heart via a delivery catheter. Hence, it would have been obvious to do so in Tantillo's method, as it is merely the substitution of one known delivery technique for another.

Claims 33, 34, and 40-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tantillo et al in view of Abbott et al 5385540. In addition to the features of Tantillo discussed above, Abbott teaches that it is known to treat a patient during bypass surgery with cardioplegia by varying the temperature and/or flow rate. Hence, it would have been obvious to modify Tantillo to vary the temperature and flow rate, to ensure that the patient gets proper treatment. In addition, Tantillo already has the temperature sensor. Claim 42 is rejected in that Abbott's system is controlled by a controller. Hence, it would have been obvious to automate Tantillo's method, to eliminate human error. Claim 46 is rejected in that Tantillo alters the site of delivery. Claim 47 is rejected in that it is the examiner's position that there must be a valve to direct the flow. In addition, with respect to claim 48, it would have been obvious to alert the physician by displaying to any changes occurring in such an automated procedure,

to provide the physician with full knowledge of the status. Claim 49 is rejected in that in order to control temperature and flow, data must be provided. Claim 50 is rejected in that the tissue is myocardial. Claim 51 is rejected in that the examiner takes official notice that it is known to deliver electrodes to the heart via a delivery catheter. Hence, it would have been obvious to do so in Tantillo's method, as it is merely the substitution of one known delivery technique for another.

Applicant's arguments filed 4/16/2008 have been fully considered but they are moot in view of the new rejection.

The examiner notes that applicant did not address the rejection based on Tantillo in the last office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
July 20, 2008

